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Attorneys for Plaintiff Shire LLC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SHIRE LLC,

Plaintiff,

v.

PAR PHARMACEUTICAL, INC. and
PAR PHARMACEUTICAL COMPANIES,
INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Shire LLC (“Shire” or “Plaintiff”), by its undersigned attorneys, brings this action against Defendants Par Pharmaceutical, Inc. (“Par”) and Par Pharmaceutical Companies, Inc. (“Par Co.”) (collectively, “Defendants”), and hereby alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendants’ submission of Abbreviated New Drug Application (“ANDA”) No. 206159 to the United States Food and Drug Administration (“FDA”). Through this ANDA, Defendants seek approval to market generic versions of the pharmaceutical product ADDERALL XR® prior to the expiration of United States Reissued Patent Nos. RE42,096 (the “’096 Patent”) and RE41,148 (the “’148 Patent”). Shire seeks injunctive relief precluding infringement, attorneys’ fees, and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky and has its principal place of business at 9200 Brookfield Ct., Suite 108, Florence, KY 41042.

3. On information and belief, Defendant Par is a corporation existing under the laws of Delaware and has a principal place of business at 1 Ram Ridge Rd., Spring Valley, NY 10977-6714.

4. On information and belief, Par is registered to do business in the State of New Jersey under Business I.D. No. 0100071541, and is a registered manufacturer and wholesaler of drugs in the State of New Jersey under Registration No. 5004032.

5. On information and belief, Par regularly conducts business in the State of New Jersey.

6. On information and belief, Defendant Par Co. is a corporation existing under the laws of Delaware and has a principal place of business at 300 Tice Blvd., Woodcliff Lake, NJ 07677-8406.

7. On information and belief, Defendant Par Co. is registered to do business in New Jersey under Business I.D. No. 0100946477.

8. On information and belief, Par is a wholly-owned subsidiary of Par Co.

9. On information and belief, Par Co. operates through its wholly-owned subsidiary Par.

10. Upon information and belief, Par Co. and Par are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic pharmaceutical products.

11. On information and belief, Par Co. and Par collaborated in the research and development of ANDA No. 206159 (“Par ANDA”), continue to collaborate in seeking approval of that application by FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale, and sale of the products described in the Par ANDA (“ANDA Products”) throughout the United States, including in the State of New Jersey, in the event FDA approves Par ANDA.

12. On information and belief, Par did not object to personal jurisdiction or venue in the District of New Jersey and purposefully availed itself of the jurisdiction by filing suit in this Court in at least *Par Pharm., Inc. et al. v. Breckenridge Pharm., Inc.*, Civ. A. No. 1:13-cv-04000 and *Par Pharm., Inc. v. Endo Pharm., Inc.*, Civ. A. No. 2:05-cv-1758; and by

filings counterclaims in this Court in at least *Jazz Pharm., Inc. v. Par Pharm., Inc.*, Civ. A. No. 14-cv-5139; *Purdue Pharm. Prods. L.P. et al. v. Par Pharm., Inc.*, Civ. A. No. 2:12-cv-06738; *Depomed Inc. v. Impax Labs., Inc. et al.*, Civ. A. No. 3:12-cv-02154; *Medeva Pharma Suisse A.G. et al. v. Par Pharm., Inc.*, Civ. A. No. 3:10-cv-04008; *Sanofi-Aventis U.S. LLC., et al. v. Mustafa Nevzat Ilac Sanayii A.S., et al.*, Civ. A. No. 3:08-cv-0263; *Novartis Corp., et al. v. Par Pharm. Cos. Inc., et al.*, Civ. A. No. 2:06-cv-4788; and *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc., et al.*, Civ. A. No. 2:06-cv-3533.

JURISDICTION AND VENUE

13. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '096 Patent and the '148 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

14. On information and belief, this Court has personal jurisdiction over Defendant Par Co. because, *inter alia*, the company maintains its principal place of business in New Jersey.

15. On information and belief, this Court has personal jurisdiction over Defendant Par because it has consented to general jurisdiction in New Jersey by registering to do business and appointing an agent to receive service of process in that state.

16. On information and belief, this Court has personal jurisdiction over Defendant Par because Par is a wholly-owned subsidiary and alter-ego of Defendant Par Co., which has its principal place of business in New Jersey.

17. On information and belief, this Court also has personal jurisdiction over Defendant Par because its continuous and systematic contacts with the New Jersey render it essentially at home in that state.

SHIRE'S PATENTS AND APPROVED ADDERALL XR® DRUG PRODUCT

18. Shire, through a corporate affiliate, makes and sells ADDERALL XR®, a widely used drug product that helps control the symptoms of Attention Deficit Hyperactivity Disorder (“ADHD”). ADHD is a condition that makes it difficult for adults and children to focus their attention, control their actions, and remain still.

19. ADDERALL XR® is a once-daily product that contains dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate. It is marketed in six dosage strengths: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. One or more claims of the asserted '096 and '148 Patents encompass ADDERALL XR®.

20. The '096 Patent, entitled “Oral Pulsed Dose Drug Delivery System,” is a reissue of U.S. Patent No. 6,322,819 (the “'819 Patent”), which issued on November 27, 2001. A true and correct copy of the '096 Patent is attached as Exhibit A. The '096 Patent discloses and claims, *inter alia*, a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts. Plaintiff Shire LLC owns the '096 Patent.

21. The '148 Patent, entitled “Oral Pulsed Dose Drug Delivery System,” is a reissue of U.S. Patent No. 6,605,300 (the “'300 Patent”), which issued on August 12, 2003. A true and correct copy of the '148 Patent is attached as Exhibit B. The '148 Patent discloses and claims, *inter alia*, a pharmaceutical formulation for the delivery of a mixture amphetamine base salts. Plaintiff Shire LLC owns the '148 Patent.

22. Shire Development LLC, an affiliate of Shire, holds New Drug Application (“NDA”) No. 21-303, under which FDA approved the marketing of ADDERALL XR® for the treatment of ADHD. FDA has listed, *inter alia*, the '096 and '148 Patents in *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “*Orange Book*”) for NDA No. 21-303 because one or more of the claims of each of those patents cover ADDERALL XR®.

DEFENDANTS’ ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

23. On information and belief, Defendants submitted or caused to be submitted ANDA No. 206159 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of the products described therein as purported generic versions of ADDERALL XR®, prior to the expiration of the '096 and '148 Patents.

24. On information and belief, on or about January 14, 2015, Par’s counsel sent Shire a Notice of Paragraph IV Certification (“Notice Letter”). The Notice Letter represented that Par had submitted to FDA the Par ANDA and a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Par ANDA before the expiration of the patents listed in the *Orange Book* for NDA No. 21-303. Hence, Defendants’ purpose in submitting the Par ANDA is to manufacture and market the ANDA Products before the expiration of the '096 and the '148 Patents. The Notice Letter also stated that the Paragraph IV Certification alleges that the '096 and the '148 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

25. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Par ANDA, have provided material support to the preparation and submission of the Par ANDA, and intend to support the further prosecution of the Par ANDA.

26. On information and belief, if FDA approves the Par ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States.

27. On information and belief, if FDA approves the Par ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products in the United States.

28. Shire brings this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Notice Letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '096 PATENT

29. Shire states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

30. On information and belief, Defendants have submitted or caused the submission of the Par ANDA to FDA, and continue to seek FDA approval of the Par ANDA.

31. Defendants have infringed the '096 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Par ANDA with a Paragraph IV Certification and seeking FDA approval of the Par ANDA prior to the expiration of the '096 Patent.

32. Defendants' commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '096 Patent.

Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206159, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '096 Patent.

33. On information and belief, upon FDA approval of ANDA No. 206159, Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals, and end users of the ANDA Products. Defendants will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for administering the ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '096 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '096 Patent and knowledge that it is encouraging infringement.

34. Defendants had actual and constructive notice of the '096 Patent prior to filing the Par ANDA with FDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '096 Patent would constitute an act of infringement of the '096 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '096 Patent. In addition, Defendants filed the Par ANDA without adequate justification for asserting the '096 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants'

conduct in certifying invalidity and non-infringement with respect to the '096 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

35. Shire will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing and contributing to the infringement of the '096 Patent. Shire does not have an adequate remedy at law, and considering the balance of hardships between Shire and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '148 PATENT

36. Shire states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

37. On information and belief, Defendants have submitted or caused the submission of the Par ANDA to FDA, and continue to seek FDA approval of the Par ANDA.

38. Defendants have infringed the '148 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Par ANDA with a Paragraph IV Certification and seeking FDA approval of the Par ANDA prior to the expiration of the '148 Patent.

39. Defendants' commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '148 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206159, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '148 Patent.

40. On information and belief, upon FDA approval of ANDA No. 206159, Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals, and end users of the ANDA Products. Defendants will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for administering the ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '148 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '148 Patent and knowledge that it is encouraging infringement.

41. Defendants had actual and constructive notice of the '148 Patent prior to filing the Par ANDA with FDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '148 Patent would constitute an act of infringement of the '148 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '148 Patent. In addition, Defendants filed the Par ANDA without adequate justification for asserting the '148 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity and non-infringement with respect to the '148 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

42. Shire will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing and contributing to the infringement of the '148 Patent. Shire does not have an adequate remedy at law, and considering the balance of hardships

between Shire and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Shire respectfully requests the following relief:

- (a) The entry of judgment, in favor of Plaintiff and against Defendants, that Defendants, through their submission of ANDA No. 206159 to FDA seeking to market the ANDA Products, have infringed the '096 and '148 Patents under 35 U.S.C. § 271(e)(2)(A);
- (b) The entry of judgment, in favor of Plaintiff and against Defendants, declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the Par ANDA, or inducing or contributing to such conduct, would constitute infringement of the '096 and '148 Patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (g);
- (c) The entry of a permanent injunction, enjoining Defendants and their officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Defendants, and their successors or assigns, from infringing, inducing infringement of, and contributing to the infringement of any claims of the '096 and '148 Patents by making, using, selling, offering for sale, or importing the ANDA Products in the United States;
- (d) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206159 shall be a date that is not earlier than the last expiration date of the '096 and '148 Patents, or any later expiration of exclusivity for the patents, including any extensions or regulatory exclusivities;

- (e) The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiff its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;
- (f) An award to Plaintiff of its costs and expenses in this action; and
- (g) Such other and further relief the Court deems just and proper.

DATED: February 26, 2015

Respectfully submitted,

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Attorneys for Plaintiff Shire LLC

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the patents asserted in the instant action are the subject of two other litigations pending in this court, *Shire LLC v. Amerigen Pharm. Ltd.*, Civ. A. No. 1:14-cv-06095 (RMB-JS) and *Shire LLC v. CorePharma, LLC*, Case No. 1:14-cv-05694 (RMB-JS). These litigations have been consolidated for purposes of all pretrial discovery and hearings at Civ. A. No. 1:14-cv-05694. (See D.I. 12, Civ. A. No. 1:14-cv-06095 (Consent Order Consolidating Case for All Pretrial Purposes)).

Dated: February 26, 2015

/s/ Sherilyn Pastor
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